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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,096	10/12/2001	Anthony David Baxter	CIBT-P02-105	1908
28120	7590	04/19/2004	EXAMINER	
ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			KIM, VICKIE Y	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/977,096

### Applicant(s)

Baxter et al

### Examiner

Vickie Kim

### Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 17-25,27-31 and 47-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-25,27-31 and 47-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. 03/31/04.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Status of Application***

1. Acknowledgement is made of amendment and terminal disclaimer filed Dec. 04, 2003. Since said amendment and terminal disclaimer comply with 37 CFR rules, they are entered properly and obvious type double patenting(ODP) rejection is overcome by terminal disclaimer and the ODP rejection has been withdrawn. Upon entering the amendment, the claims 1-16, 26, 32-46, 53, and 59-63 are canceled.
2. The claims 17-25, 27-31, 47-52, 54-58 are pending and presented for the examination.
3. It is noted that the offer made by the examiner to put the case under the allowable condition(see interview summary, March 31, 2004) is withdrawn as upon finding particularly relevant prior art where new ground rejection is necessitated to carry out complete examination.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting

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directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 17-25, 27-28, 31, 47-52, 54-55, 58 are rejected under 35 U.S.C. 102(e) as being anticipated by Ling et al(US 2003/0022819 A1).

The claims are drawn to a pharmaceutical composition in aqueous solution containing the compound having the general structure of formulas (II) or (IV) as recited in the instant claim 17 and 47.

Ling et al(US'819, hereafter) teaches a pharmaceutical composition in the form of aqueous solution for topical administration (paragraph 560 and 563 at pages 36-37) comprising a hedgehog agonist or antagonist as an active agent wherein the agent is represented by general formula formulas VII or IX(see page 21, paragraphs 287-299). All the possible substituents on each position are well taught by the reference, see pages 16-20.

As to the claims 25 and 28, the active agent is used in the form of pharmaceutically acceptable salts such as lactate, maleate. The composition comprises a pharmaceutically acceptable carrier such as dextrose, see paragraph 561-562 at pages 36-37.

Thus, all the critical elements required by the instant claims are well taught and the claims are not patentably distinct over the prior art of the record.

***Claim Rejections - 35 USC § 103***

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6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 29-30 and 56-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ling et al (US'2003/0022819).

The teaching of Ling et al(US'819) is mentioned immediately above in the 102 rejection.

Applicants claims differ because they require specific osmolarity(i.e. 200-400mOsm) or pH in the range of 3-6.

However, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify the composition of US'819 to include those said pH and osmolarity required by the instant claims because the said modification involves conventional techniques and skills known to pharmaceutical industry, and one would have been motivated to make such modification because optimization of osmolarity and pH adjustment based on the formulation and routes of administration used in the treatment is critical in order to maximize the therapeutic efficacy. Furthermore, it is always desirable and marketable to have pharmaceutically acceptable and physiologically compatible product. Especially, US'819 utilizes an osmotic pump where any skilled artisan would have optimized the osmolarity of solution to produce for the

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reasons set forth earlier. US'819 also acknowledges that the hedgehog protein is most reactive in neutral or acidic pH(e.g. 7.5-6), see column 26, paragraph 390. Thus, one would have been motivated to adjust pH of the solution to optimal pH range by anticipating the chemistry and the pharmacology of therapeutics.

One would have been motivated to make such modification, with reasonable expectation of success, because the techniques and skills to make the said modification is well known to medicinal chemists, absent evidence to the contrary.

### ***Conclusion***

8. No claim is allowed.

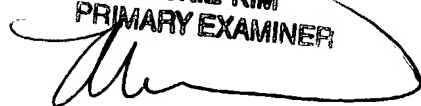
9. This is non-final action because new ground of rejection is issued over newly introduced prior art of the record.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579(fax: 571-273-0579). The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 571-272-0584. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

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**VICKIE KIM**  
**PRIMARY EXAMINER**  


Vickie Kim  
April 13, 2004  
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